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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040421

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Application Number: 09/937,534
Filing Date: September 26, 2001
Appellant(s): BRACHT, STEFAN

Bruce Hamburg
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/22/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-36,8,and 14-16 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

3,559,655	BRISKEN et al	02-1971
4,039,653	DEFONEY et al	08-1977
5,362,496	BAKER et al	11-1994
5,559,554	MAJETI	02-1997
5,820,877	YAMAGUCHI et al	10-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3, 14 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Baker et al (USPN 5,362,496 hereafter '496), Yamaguchi et al (USPN 5,820,877 hereafter '877) and Majeti (USPN 5,599,544 hereafter '544). The claims are drawn to a transdermal therapeutic system (TTS) comprising a backing layer and an adhesive patch, where the patch comprises nicotine as a drug and a monoterpene ketone or essential oil containing a ketone. The claims also recite specific concentrations of the monoterpene ketones present in the invention.

The '496 patent teaches a transdermal formulation comprising a backing layer and an adhesive matrix layer. The reference also discloses transmucosal formulations, which include further flavoring/taste masking compounds (col. 15, lin 39- col. 18, lin. 21). The compounds are well known for scent masking as well, specifically peppermint and carvone (col. 20, lin. 26-32). The preferred, though not limiting presentation is a gum, lozenge or tablet, yet ointments and lotions are also disclosed. The transdermal formulation includes nicotine as a drug and essential oils. The essential oils suggested are spearmint and peppermint oil, along with monoterpene

ketones and alcohols such as 1-menthol and carvone (col. 6, lin. 6 – 59; col. 20, lin. 26 – 36). The reference states the formulation can be made into both transmucosal and transdermal formulations. Though the reference discloses transmucosal delivery of nicotine and carvone, it does not disclose the formulation in a patch presentation.

The '877 patent teaches a percutaneous or mucosal patch comprising a backing layer, release liner, an adhesive layer and nicotine as a drug. The patch further teaches that monoterpene alcohols may be used as absorption enhancers, specifically menthol and mentha oil (col. 4, lin. 18 – 57). The patch is however silent to the inclusion of monoterpene ketones. The '877 patent establishes the knowledge in the art, that skilled artisan's are able to present oral mucosal patches comprising nicotine and essential oils. A skilled artisan would follow this motivation as evidenced by '877 to combine the transmucosal formulation of '496 into the patch device of '877.

The '544 patent teaches transdermal or transmucosal delivery system where the formulation comprises nicotine, and menthol as an additive. The reference also teaches that the delivery system further comprises a backing layer (Abstract; col. 6, lin. 6 – 21). The reference establishes the art recognized nexus between transdermal and transmucosal formulations. A skilled artisan would have followed this motivation to expect a reasonable level of success of a transmucosal nicotine patch by combining the nicotine/carvone formulation of '496 into the transmucosal patches of '877, since '544 discloses many of the same support excipients (cellulose polymers) (col. 4, lin. 59-col. 5, lin. 31). Sharing carrier excipients such as disintegrants, polymers and binders, shows the compatibility of two formulations. For example all formulations comprise polyvinylpyrrolidone, a common excipient in mucosal delivery, as a

carrier polymer. Since a formulation shares similar polymers, a skilled artisan would expect similar results in transitioning from one device or delivery method to another, since the formulations remain essentially the same.

With regard to the concentration limitations of claims 1 and 15, it is the position of the examiner that these concentrations do not impart patentability on the formulation of applicant. The prior art presents a general combination of components, where applicant merely presents the best mode of their combination, found through routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind a skilled artisan would have been motivated to combine the teachings of the art and modify them to provide an optimal presentation. '496 provides a transmucosal formulation comprising nicotine, flavor/taste making agents such as menthol or carvone, and where both monoterpene alcohols and ketones were suggested (menthol, and carvone), and could be used interchangeably. A skilled artisan would have followed the suggestion of '877 to include menthol and other monoterpene alcohols into transdermal formulations. Though known

in the art, '554 would have provided the teaching that, formulations for both transdermal and transmucosal delivery are interchangeable and can be prepared similarly. With these suggestions a skilled artisan could have used the structure and support of the backing layer, of either '496 or '877, in order to impart support onto the preparation. The artisan would have used the release liner of either '496 or '877 as well. This would have been motivation enough for a skilled artisan to include either carvone or menthol into a transdermal preparation comprising nicotine in order to provide better absorption. It would have been obvious to one of ordinary skill in the art to do this with an expected result of a TTS with a supporting backing layer, a release liner, along with an adhesive matrix comprising nicotine and carvone.

1. Claims 6, 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Baker et al (USPN 5,362,496 hereafter '496), Yamaguchi et al (USPN 5,820,877 hereafter '877) and Majeti (USPN 5,599,544 hereafter '544) in view of Brisken et al (USPN 3,559,655 hereafter '655) and DeFoney et al (USPN 4,039,653 hereafter '653).

The claims are drawn to a process for masking the smell of a nicotine containing transdermal patch. The claims recite a specific concentration for a monoterpene ketone used to mask the smell of the nicotine.

As previously discussed above the combination of the teachings of '496, '877, and '554 render the claimed invention obvious. The composition teaches a transmucosal patch comprising nicotine and carvone, where the patch has a release liner, and backing. It is known in the art that mint oil and extracts (monoterpene ketone included) have odor and taste masking properties. As seen in '653 (col. 9, lin. 15 – 20) and '655 (col. 7, lin. 1 – 5) it is recognized in the art that these substances mask odors when introduced into formulations. Their presence in the

combination discussed above, would inherently mask the odor of the surrounding constituents. Though not disclosed by the reference, given the inherent odor-masking properties of mint oils, and extracts, one of ordinary skill in the art would have been motivated to follow the knowledge in the art in order to mask the odor of the constituents of the TTS. It is the position of the examiner that this combination also renders the claimed process obvious, by the inherent taste/flavor masking properties of the constituents. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the knowledge in the art with the expected result of a TTS comprising a suitable backing, and protective layer, useful nicotine suppression therapy.

Regarding the claims 6 and 16, which recite specific concentrations of the monoterpene ketone used for the invention, it is the position of the examiner that these concentrations do not impart patentability on the formulation of applicant. The prior art presents a general combination of components, where applicant merely presents the best mode of their combination, found through routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges

is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to one of ordinary skill in the art to follow the teachings and suggestions of the art. A skilled artisan would have been motivated to use the products of the combination of '496, '877, and '554 to mask the smells of nicotine present in transdermal formulations. '653 and '655 provides support and teachings that mint oils and their extracts provide taste and odor masking properties to the formulations to which they are added. A skilled artisan would have been motivated to combine these references in order to mask the offensive odor of nicotine. It would have been obvious to one of ordinary skill in the art to combine these references with an expected result of transdermal formulation for smoking cessation, comprising nicotine and an amount of mint oil extracts sufficient to mask the odor of the nicotine.

(11) Response to Argument

Issue No. 1

Applicant argues that '496 does not explicitly teach a transdermal formulation containing a monoterpene ketone, only a transmucosal formulation in the form of a lozenge.

Applicant argues that The secondary reference do not remedy this problem, since '496 only teaches lozenges and no other transmucosal formulation, the combination does not obviate the invention.

In response it is the position of the examiner that the combination of '496, '887 and '554 provide a combination sufficient to obviate the claimed invention. '496 provides formulation for the transdermal delivery of nicotine. Also disclosed in the reference are transmucosal

formulations such as lozenges. Ointments, and gels are also disclosed as possible presentations. Applicant takes a far too narrow interpretation of the art and does not take into consideration that the examples in the specification do not limit the scope of the invention once the concept is well known.

The '554 patent provides evidence that it is known in the art to combine taste/scent masking compounds with nicotine and deliver them transmucosally in a fully realized structure. As evidenced by the '554 patent, transmucosal or transdermal preparations are manufactured and applied comprising nicotine and 1-menthol (a compound recited by applicant to be congruent to the scent/taste masking compounds of the instant claims).

The '887 patent provides a simple structure to deliver a wide array of compounds transdermally or transmucosally. The matrices of '887 and '496 are nearly identical and the only difference being the active ingredients, though these components are inconsequential since applicant has not placed any emphasis on the make of the supporting matrix. An artisan would have been motivated to combine the teachings in order to provide a stable delivery device for the transmucosal formulation of '496. It would be well within the level of skill in the art to apply the transmucosal formulation of '496 into the device of '887, since they share similar active agents and carrier excipients. A skilled artisan would expect the transmucosal formulation of '496 comprising nicotine and carrier polymers to be successfully transferable into the device of '877 since it can deliver formulations comprising nicotine and various common carrier polymers. A skilled artisan would have found further motivation in '554, which provides a connection between the transmucosal and transdermal delivery of smoking succession formulation. The '877 patent provides the structure of the device and '544 provides evidence of the nexus between

transdermal and transmucosal devices having carrier polymers and nicotine. Compounds such as carvone and essential oils are well known for their taste/scent masking properties. This is evidenced by their use in candy and confection compositions, especially breath freshening compositions. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. Applicant has ignored the combination of the transmucosal formulation of'496 into the delivery device of '877, under the knowledge evidenced by '544. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Issue No. 2

Applicant argues that since the combination of '496, '887 and '554, the addition of '655 and '653 is erroneous and does not remedy the deficiencies of the combination.

In response to this argument, it is the position of the examiner that, the addition of these references simply supports earlier claims of obviousness over the claimed invention. '655 and '653 are used to merely support what is known in the art, that monoterpene ketones are well known scent/taste-masking compounds. It is the position of the examiner that the presence of carvone in the combination would inherently mask the scent of any harsh flavors or scents. The references '655 and '653 simply provide teachings to that effect. Again applicant provides a piecemeal analysis of the references, when the rejection is based on the combination of reverences.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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May 18, 2004

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